



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,643	04/04/2006	Xiong Chen	4390-0113PUS1	4099
2252	7590	01/09/2009		
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
			EXAMINER	
			HOBBS, LISA JOE	
			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			01/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/574,643	Applicant(s) CHEN ET AL.
	Examiner Lisa J. Hobbs	Art Unit 1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 October 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6,7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 2, 4, 6, 7, 10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-166/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-2, 4, 6-7, and 10 are active in the case. Claims 3, 5, 8-9 and 11-13 have been cancelled by amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 1-3, 4, 7, 10, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by DiGiorgio et al. (US 5,804,402) is withdrawn in view of the amendments to the claims in the response of 01 October 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6-7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGiorgi et al. (US 5,804,402), DiGiorgio et al. (5,705,356) and Cozzette (US 6306594). As discussed previously, in the '402 patent, DiGiorgio et al. teach a reagent for the determination of an analyte concentration in a patient wherein the degree of oxidation of a coenzyme is measured, characterized in that said reagent is stabilized against oxidation by a coenzyme reduction system comprising an enzyme and a substrate pair selected so as to enable continuous regeneration of said coenzyme throughout storage of said reagent, said enzyme having incomplete specificity for said substrate such that there is no loss in functionality of the reagent in the determination of analyte concentration throughout at least 6-8 months of storage of said reagent at 2 °C -8 °C. They do not teach the specific concentrations recited in the dependent claims. DiGiorgio et al. teach additional information in the '356 patent, comprising testing to determine the proper regeneration levels of enzyme/substrate (col. 10, lines 16-46).

Cozzette et al. teach microfabricated biosensors, methods and materials for the mass production thereof, and their use in the determination of the presence and/or concentration of a variety of selected analyte species. In particular, the integrated biosensors of the present

invention may be manufactured by a process which allows the incorporation of a variety of bioactive molecules, which bioactive molecules provide the basis of the analytical technique, through the use of materials which are compatible with the bioactive molecules and which materials have been especially adapted for that purpose. The integrated biosensors of the instant invention are also fully compatible with undiluted biological fluids and may be utilized in a wide range of medical, as well as nonmedical, applications.

They also teach electrochemical assay procedures useful in determining the presence and/or concentration of biological species (analytes) of interest and the use of a non-electroactive substrate that does not undergo detectable oxidation or reduction at an electrode's operating potential, but which substrate undergoes a reaction with a substrate converter which gives rise to changes in the concentration of detectable electroactive species, these changes are measured and related to the concentration of the biological species of interest (col. 1, lines 19-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of DiGiorgio et al. ('402 and '356) and Cozzette et al. in order to achieve the invention as claimed. The art teaches that it is well known to fabricate sensors that measure the concentration of an analyte of choice, using an enzyme/substrate pair of choice, and choosing a regenerating system so that the sensor is able to perform multiple measurements. One of skill would be able to use the teachings to arrive at the levels of reagent recited through simple experimentation, as outlined by DiGiorgio et al. and Cozzette et al. One would have a reasonable expectation of success since the use of sensors such as those recited in the cited art and other well-known examples such as BUN/creatinine sensors is known to those of skill.

Response to Arguments

Applicant's arguments filed 01 October 2008 have been fully considered but they are not persuasive. Applicants argue that De Giorgio does not teach the levels of GDH and D-Glc now claimed in the independent claim. However applicants discuss that he “[utilizes] a large range of concentrations of [GDH] and [D-Glc], as the office action also discusses, stating that he teaches information “comprising testing to determine the proper regeneration levels of enzyme/substrate (col. 10, lines 16-46).” Applicants argue that the amounts recited in the claims were empirically determined by Applicants, however De Giorgio discloses determining the desired range of enzyme concentration to achieve the proper pair activity level. He also states that other enzymes such as MDH and PEPC (see col. 10) can be used at low levels similar to those now recited in the claims. De Giorgio also recites that stability in storage is a factor in deciding the levels of enzyme to be used (see col. 11).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh